

REMARKS

In the Office Action dated January 16, 2009, the Examiner rejected claims 1-11, 15-19, and 21.

1. Amendments to the Claims

Claim 1 is amended. Support for the amendments to claim 1 is found in the Specification at page 4, lines 1-4, and original claims 1 and 2.

New claim 23 is added. Support for claim 23 is found in the Specification on page 1, line 20, page 8 lines 4-5.

New claim 24 is added. Support for claim 24 is found in the Specification at Example 2, and in Original claims 1 and 3.

New claim 25 is added. Support for new claim 25 is found in Original claim 1.

New claim 26 is added. Support for claim 26 is found in the Specification at page 4, line 6.

New claim 27 is added. Support for claim 27 is found in the Specification at page 5, line 23.

New claim 28 is added. Support for claim 28 can bee found in Examples 2 and 3, beginning on page 7.

New claim 29 is added. Support for claim 29 can be found in the Specification at page 8, Example 3.

New claim 30 is added. Support for new claim 30 is found in the Specification at page 4, line 4 (single reaction step and single precipitation step).

No new matter has been added.

2. 35 U.S.C. §112 Written Description

The Examiner rejects claims 1-11, 15-19, and 21 as lacking sufficient written description. The Examiner states that “[n]o basis or support is found in the present specification for phosphatidyl-L-serine sodium salt having a purity of over 95%.” (Office Action, page 2).

Applicants respectfully submit that the sodium salt is implicitly disclosed in the process. As detailed in the Amendment of October 22, 2008, the process as described in the examples results in a phosphatidyl-L-Serine sodium salt. Applicants submit that one of skill in the art, reviewing the process described in the examples would recognize that the product is a phosphatidyl serine sodium salt. Furthermore, this is further supported by the basic knowledge of phosphatidyl serine. Applicants attach an article by Folch showing that bases (i.e., sodium acetate) combined with phosphatidyl serine (i.e., the phosphatidyl serine sodium salt) can be removed by the use of 0.05 N HCL. (See Folch, JBC 174 (2): 439 (1948) at page 440, lines 16-20 and page 444, lines 29-31). Therefore, phosphatidyl serine salt is made from the PS free acid by the addition of the base required (i.e., sodium acetate). Accordingly, when one skilled in the art reads, as in Example 2 of the present Specification, that “[t]he organic phases are . . . precipitated by slowly adding a solution of . . . sodium acetate, 4.5 M” (Specification, page 8, lines 1-2), he or she would recognize that the phosphatidyl serine recovered is a phosphatidyl serine sodium salt.

Moreover, the Specification recites that the product, the phosphatidyl serine sodium salt, has a titer of “over 95%” at page 8, lines 4 and 27. Thus, Applicants submit that there is sufficient support for the statement that the phosphatidyl-L-serine sodium salt is “over 95% pure.”¹

As written description is always taken with the understanding that possession is determined by one of ordinary skill in the art, (MPEP 2163 (I)), it is appropriate to establish what the knowledge of one of skill in the art would be. In addition, “the description need only describe in detail that which is new or not conventional.” (MPEP 2163 (II)(A)(3)(a), citing *Hybritech v.*

¹ The statement the Examiner points to from the prior response on page 3 of the Office Action was not intended and did not indicate that Applicants agreed that “over 95%” was not supported by the Specification. The Examiner has merely taken the statement incorrectly.

Monoclonal Antibodies, 802 F.2d 1367, 1384 (Fed. Cir. 1986)). “the claimed subject matter need not be described *in haec verba* in the specification in order for that specification to satisfy the description requirement.” *In re Wright*, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989). “The fact that the exact words here in question . . . are not in the specification is not important.” *Id.* In addition, Applicants are not required to show an unequivocal teaching that the claimed language is in the Specification. *Id.* Instead, the determination of whether there is sufficient written description is based on what one of skill would have understood from the disclosure in the Specification and the knowledge in the art.

As discussed above, Applicants have established that as early as 1948, one of skill would have recognized that the process described produces a phosphatidyl serine sodium salt. Applicants describe the process, and provide working examples of how to achieve the claimed product. Accordingly, Applicants submit that the Specification sufficiently discloses a phosphatidyl serine salt which is over 95% pure, and that one of skill in the art would clearly have recognized this from the teachings of the Specification. Applicants respectfully request that the rejection be withdrawn.

3. 35 U.S.C. §112 Indefiniteness

The Examiner rejects claims 5-6 and 21 as indefinite. The Examiner states that claims 5-6 appear internally inconsistent in being directed to a sodium salt, yet the RI moiety is hydroxyl. Applicants submit that the claim is definite. As discussed above, the specification discloses a phosphatidyl serine sodium salt. The claims recite a phosphatidyl serine sodium salt of the phosphatidyl serine formula presented in formula I. Thus, the claim does not encompass the phosphatidyl-serine of formula I, it does encompass the sodium salt of formula I. Accordingly Applicants submit that the claim is definite and clear.

4. **35 U.S.C. §102/103**

Anticipation

The Examiner rejects claims 5-11 and 15-19 as anticipated by Sakai. The Examiner states that Sakai discloses a phosphatidyl-L-serine composition which contains a phosphatidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. . . . Inasmuch as sodium phosphate buffer is used, phosphatidyl-L-serine sodium salt is present at least to some extent.” (Office Action, page 4). Applicants respectfully disagree.

Sakai does not disclose a composition having a purity of 95% or more, and with a degree of peroxidation of less than 5. The Examiner states that the patent and trademark office has not the resources to compare the product of Sakai with the product of the claimed invention and states that Applicants have not provided evidence suggesting that the products are different. However, Applicants have provided evidence in the form of the Declaration of Dr. Menon. Dr. Menon tested both processes disclosed in Sakai to determine what their products were. With regard to the first process, Dr. Menon found that the product was only 40% pure phosphatidyl serine. Thus, the product is DIFFERENT, than the product of the claimed invention, which is over 95% pure phosphatidyl serine sodium salt. (Menon Declaration page 2, paragraph 3). With regard to the second process, Dr. Menon showed that Sakai did not work, i.e. it did not produce a product because nothing eluted from the column in the second part of the Sakai process. (See Menon Declaration, page 2, paragraph 4). Thus, Sakai does not disclose a product which is over 95% pure phosphatidyl serine sodium salt.

Moreover, Applicants submit that Sakai is not an enabling disclosure. “The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.” (MPEP 2121.01, *citing Elan Pharm. Inc., v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 68 USPQ2d 1373 (Fed. Cir. 2003), *see also* MPEP

2121.02). As the Menon Declaration establishes that the process of Sakai did not produce the claimed composition, and that even modifications to the process of Sakai did not produce the claimed composition, Applicants submit that any *prima facie* case of anticipation has been rebutted. Applicants request that the rejection be withdrawn.

The Examiner states “[t]hat the reference [Sakai] does not disclose a phosphatidyl-L-serine sodium salt of 95% purity or more is not disputed. However the compositions therein contain this material and the purity thereof cannot be readily assessed even in light of the Menon experiments.” (Office Action, page 7). First, Applicants agree that Sakai does not disclose the claimed invention, and thank the Examiner for recognizing that fact. However, the burden is on the Examiner to establish that the references disclose each and every feature of the claimed invention. As Applicants have established that one of skill in the art could not make and use the invention based on the disclosure of Sakai, Sakai cannot be used to establish an anticipation rejection, and as discussed below, should not be used as the basis for an obviousness rejection. Moreover, the Examiner’s dismissal of the Menon declaration is an impermissible substitution of his judgment for that of one of skill in the art. Thus, Applicants request that the rejection be withdrawn.

Obviousness

The Examiner further rejects claims 1-11, 15-20, and 21 as being obvious in light of Sakai, taken with De Ferra and Horrobin, Puricelli, Chemical Land21, and Kurihara et al..

The MPEP states that “rebuttal evidence may include a showing that the prior art fails to disclose or render obvious for making the compound, which would preclude a conclusion of obviousness of the compound.” (MPEP 2145). As discussed above, one of skill could not make the claimed product based on Sakai, as shown by the Menon Declaration. The combination of Sakai, De Ferra, Horrobin, Puricelli, Chemical Land 21 and Kurihara does not show a product that is over 95% pure phosphatidyl-L-serine sodium salt. The Examiner has not established that this

characteristic is present in any of the cited references. Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. Applicants request that the rejection be withdrawn.

Moreover, the Examiner's reliance on the "scope of the showing must be commensurate in scope with the claims" does not obviate the requirement that the PTO establish that the prior art references necessarily disclose a product that is over 95% pure phosphatidyl-L-serine sodium salt. Applicants have established that Sakai does not disclose this product through the Menon Declaration.

The Examiner states that "the claims are not directed to a phosphatidyl-L-serine product consisting of choline." Applicants submit that the head group of the fatty acid is converted during the process of the claims from phosphatidyl choline to obtain phosphatidyl-L-serine sodium salt. Thus, Applicants are confused by the Examiner's statement and submit that the Examiner has misinterpreted previous arguments.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Conclusion

In view of the above remarks, it is believed that claims are allowable.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1,110.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the

Application No. 10/663,198
Amendment dated July 15, 2009
Response to Non-Final Office Action of January 16, 2009

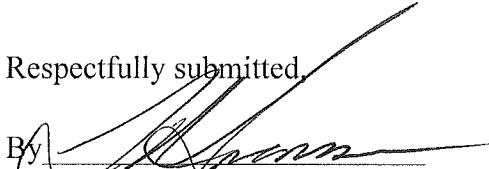
Docket No.: 0259-0417P

telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: July 15, 2009

Respectfully submitted,


By _____
Leonard R. Svensson

Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant

Attachments: Folch (1948)